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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,133	09/19/2003	Howard M. Johnson	UF-243XD1	7182

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,133	JOHNSON ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response Applicants response filed 12/1/2005. Claims 36-38 have been added. Thus, claims 20-38 are pending and under consideration in this action.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Priority

3. Applicants have updated the priority information.

Claim Rejections - 35 USC § 112, maintained

4. The rejection of claims 20-38 under 35 U.S.C 112, first paragraph, as lacking enablement is maintained for reasons set forth in the Office Action dated 7/27/05 (pages 2-3). Specifically Office indicated that the Applicants are not enabled for biologically active fragments of interferon tau. Applicants assert that one of skilled in the art, having the benefit of the teaching of the subject application, can readily produce fragments of the various interferon proteins and test those fragments for biological activity. Applicants contend that the level of skill of a person in the biotechnology arts is high and methods for preparing fragments of a protein are well known in the art. In addition, Applicants contend that methods for testing the fragments to determine if they have the requisite biological activity are disclosed in the subject specification. Applicants also argue that while some experimentation may be necessary, it is not controlling on the issue of enablement where the experimentation is routine. They cite *Ex parte Jackson* support their argument. They also discuss *In re Wands*. Thus, it is claimed by the Applicants

that preparation of protein fragments and testing thereof for biological activity is routine. Applicants' arguments have been fully considered but are not found to be persuasive.

The broad-brush discussion of making and screening for fragments does not constitute a disclosure of a representative number of members. No such variants were made or shown to have activity. Only the interferon tau protein is disclosed. Applicants have not disclosed interferon tau region required to retain specific biological activities. According to MPEP § 2164.06, "the guidance and ease in carrying out an assay to achieve the claimed objectives may be an issue to be considered in determining the quantity of experimentation needed. For example, if a very difficult and time consuming assay is needed to identify a compound within the scope of the claim, then this great quantity of experimentation should be considered in the overall analysis". The specification's general discussion of making and screening for variants constitutes an invitation to experiment by trial and error. Such trial and error experimentation is considered undue. Certain positions in the polypeptide sequence are critical to the protein's structure/function relationship, e.g., such as various sites or regions directly involved in binding, activity, and in providing the correct three-dimensional spatial orientation of binding and active sites. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone. However, Applicant

has provided little or no guidance beyond the mere recitation of interferon tau protein to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the interferon tau protein which are tolerant to change (e.g. such as by deleting regions of the polypeptide), and the nature and extent of changes that can be made in these positions. Contrary to Applicants assertion that what is required in the instant invention is routine screening to generate the biologically active fragments, in the absence of guidance for regions required to retain biological activity, a large quantity of experimentation would be required by the skilled artisan to generate the infinite number of biologically active fragments of interferon tau recited in the claims and screen the same for activity. This is undue experimentation. Ex parte Jackson also found that although considerable experimentation is permissible "undue" experimentation is not. As was found in Ex parte Hitzeman, 9 USPQ2d 1821 (BPAI 1987), a single embodiment may provide broad enablement in cases involving predictable factors such as mechanical or electrical elements, but more will be required in cases that involve unpredictable factors such as most chemical reactions and physiological activity. See also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991).

Thus, the skilled artisan would not be able to determine, without undue experimentation, the structural conformation and function of interferon tau fragments based upon linear amino acid sequences only. One skilled in the art would also not be able to determine, without undue experimentation, the regions of interferon tau protein,

which are tolerant to change (e.g. such as by deletions), and the nature and extent of changes that can be made in these positions. Therefore rejections of record are maintained.

5. The rejection of claims 20-38 under 35 U.S.C 112, first paragraph, as lacking written descrition is maintained for reasons set forth in the Office Action dated 7/27/05 (pages 3-4). Specifically Office indicated that the Applicants had possession of the various biologically active fragments of interferon tau (No written description). Applicants assert that there is adequate written description in the subject specification to convey to the ordinary skilled artisan that they had possession of the claimed invention. Applicants contend that interferon tau proteins are well characterized in the art in regard to their structural and functional features. Applicant states that the primary amino acid sequence of interferon tau is well known in the art and methods for preparing fragments from a full-length protein are also well known in the art. Thus, Applicants claim that the structure of any fragment of interferon tau is known in the art and every fragment can be tested for function, i.e., biological activity as recited in the claims, without resorting to undue experimentation.

Thus, it is claimed by the Applicants that the specification provides written description for interferon tau protein fragments. In addition, Applicants recite *Hybritech v. Monoclonal Antibodies, Inc.,* 231 USPQ81 (Fed. Cir. 1986), which involves primarily USC112, enablement issue and not written description issues and offers no support to Applicants position. Furthermore, Applicants appear to take out of context the statement

"It is well settled in patent law that an application need not teach, and preferably omits, that which is well known in the conventional art". Applicants' arguments have been fully considered but are not found to be persuasive.

While it is true that the amino acid sequence of interferon tau in known in the art and methods of making fragments are also known in the art, there is no correlation of function to the structure. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In addition, it is noted that MPEP 2163 [R-2] IA states that "The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence". In the instant invention Applicants have not described a correlation or relationship between structure and function.

6. The rejection of claims 20-38 under 35 U.S.C 112, second paragraph, as indefinite is maintained for reasons set forth in the Office Action dated 7/27/05 (page 4).

Applicants are correct in pointing that Office incorrectly referred to a "to a person or animal in need of suppression of inhibition of alleregen-specific IgE production" to "IgE-related condition". Applicants' arguments (page 8, 2nd paragraph of 12/1/2005) have been fully considered but are not found to be persuasive. Since, IgE is presumably involved in various conditions it remains unclear why and when allergen-specific IgE production needs to be suppressed or inhibited. It is unclear in claim 28 why or when one would want to suppress or inhibit proliferation of an IgE-producing cell. Claims 21-27 and 29-34 remain rejected under 35 U.S.C 112, second paragraph, as being indefinite.

Claim Rejections - 35 USC § 102, maintained

7. The rejection of claims 20, 22-35 and newly added 36-38 under 35 U.S. C 102 as being anticipated by Soos et al. (U.S Patent No; 5, 908,816) is maintained for reasons set forth in the Office Action dated 7/2/2005 pages 5-6. Applicants assert, however, that the '816 patent does not teach or suggest treatment of a person that has an autoimmume disorder and who is need of inhibition of allergen-specific IgE production or inhibition of proliferation of IgE producing cells. It is further claimed that the Examiner has not pointed to evidence in the art of a person having both an autoimmune disorder and who is also in need of inhibition of allergen-specific IgE production or inhibition of proliferation of IgE producing cells. Further Applicants assert that a person may suffer from both an autoimmune disorder and a disorder that involves allergen-specific IgE production or proliferation of IgE producing cells, does not lessen or remove the legal

requirement that in order to anticipate under 35 USC 102, a single reference must teach each and every element of the claimed invention. Applicants also cite *Scripps Clinic & Research Foundation v. Genentech, Inc.*, to argue that a single reference must disclose within the four corners of the document each and every element and limitation contained in the rejected claim. Applicants' arguments have been fully considered but are not found to be persuasive.

While it is true that '816 patent does not teach the suppression or inhibiting allergen-specific IgE production by administering interferon-tau, as indicated in the Office Action of 7/2/05 page 5, such treatment would inherently result in the suppression of IgE production, regardless of whether this suppression or mechanism by which it was achieved was recognized. In the instant application, inherency is established by Applicant's own disclosure. According to Applicant's teachings, beneficial effects on IgE-mediated allergy result from the administration of interferon tau. The Examiner does not question these results. However, there is nothing in Applicant's methods that differentiates them from what is taught by the prior art, and the patient populations of the prior art would include sufferers from IgE-mediated allergy. This is because sufferers from autoimmune disease and sufferers from immune system disorders, including allergy, would include a population suffering from IgE-related allergy and such allergies would inherently have been treated by the methods of '816 patent, regardless of whether the effect was recognized at the time. Thus they would have inherently been treated for this condition regardless of whether that fact was recognized at the time. Although Soos et al. may not have appreciated the full mechanisms of interferon tau

administration; the method of treatment itself nonetheless meets the limitations of the claims. Therefore, the Office does not contradict the observations of *Scripps Clinic & Research Foundation v. Genentech, Inc.* Despite the fact that applicants may have been the first to characterize the suppression or inhibiting allergen-specific IgE production by interferon-tau, that effect would inherently have occurred in the population treated by Soos et al. The Examiner notes the decision in *Swinehart and Sfiligoj*, 169 USPQ 226, in which it was found that mere recitation of a newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art. Although the prior art did not necessarily appreciate the mechanism by which the effect was attained, it clearly teaches the same method, using the same active agent, as the rejected claims. Therefore, inhibition of allergen-specific IgE production must have been inherently occurring in the prior art of Soos et al. (see *Ex parte Novitski*, 26 USPQ2d 1389 (BPAI 1993); see also *Integra LifeSciences I Ltd. V. Merck KGaA*, (DC SCalif) 50 USPQ2d 1846). The broad method steps claimed in the instant application are the same as the steps disclosed in Soos et al. Thus, Soos et al. anticipate the claimed invention of the instant application.

Furthermore, inherent anticipation does not require that one of ordinary skill in the art recognize an inherent feature in a prior art disclosure (*Schering Corp. v. Geneva Pharmaceuticals Inc.*, 67 USPQ2d 1664 (CAFC 2003); *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)). Regardless of whether Soos et al. disclosed interferon tau as suppressing or inhibiting proliferation of IgE producing cells, suppression or inhibition would have been inherent to the

administration to interferon tau. Thus meeting the limitations of claim 28. With respect to claim 35, the disclosure of interferon administration in would inherently have resulted in the suppression or inhibition of allergen-specific IgE production regardless of the need for suppression.

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using (see *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated (see *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). Regarding the instant application, since Soos et al. teach the administration of interferon tau to treat immune disorder (see column 5, lines 45-55) as recited in the claims, suppression or inhibition of allergen-specific IgE production must have been inherently occurring in the prior art. That is sufferers from autoimmune disease and sufferers from immune system disorders, including allergy, would include a population suffering from IgE-related allergy and such allergies would inherently have been treated by the methods of '816 patent, regardless of whether the effect was recognized at the time. Therefore, the disclosure of Soos et al. fully meets the terms of the claimed method because interferon tau inherently possesses suppression or inhibition of allergen-specific IgE production activity. A compound and all of its properties are inseparable; they are one and the same thing and simply stating a new property of interferon tau does not render the claimed method of inhibiting angiogenesis of the instant application free of the art (see

In re Papesch, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169 USPQ 226 (CCPA 1971); *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978)). Furthermore the limitations of claim 36-37 are taught in columns 7, 8, 13 and 15. Therefore the rejection of claims 20 and 22-38 under 35 U.S. C 102 as being anticipated by Soos et al. (U.S Patent No; 5, 908,816) is maintained.

8. The rejection of claims 20, 21, 27, 28, 34 and 35 under 35 U.S. C 102 as being anticipated by Mujtaba et al (1998) is maintained for reasons set forth in the Office Action dated 7/2/2005 page 6. Applicants assert, the Mujtaba et al. reference does not teach or suggest administering interferon tau to a person or animal in need of suppression or inhibition of allergen-specific IgE production or proliferation of IgE-producing cells, nor does the cited reference teach or suggest the first step set forth in the claimed method, i.e., identifying a person or animal in need of suppression or inhibition of allergen-specific IgE production. Applicants assert that there is no relation between EAE and allergen-specific IgE production or proliferation of IgE-producing cells. Applicants also assert that there is no teaching or suggestion in the Mujtaba et. al. reference that the mice also had a disorder involving allergen-specific IgE production or proliferation of IgE-producing cells. Thus, it is asserted that the cited reference does not teach or suggest identifying a person or animal in need of suppression or inhibition of allergen-specific IgE production, nor does it teach or suggest administering an effective amount of interferon tau to the identified person or animal.

Applicants also discuss *Saltech Inc.* case (see page 11 of the response filed 12/01/2005). Applicants also discuss immunoglobulins and specifically discuss IgE. It is concluded by the Applicants that inhibition or suppression of allergen-specific IgE production or proliferation of IgE-producing cells by interferon tau was not "inherent" in the disclosure of the treatment patients Mujtaba et al. reference. Applicants' arguments have been fully considered but are not found to be persuasive.

What was at issue in *Scaltech* was whether the property actually existed, not whether it was recognized:

> If the process that was offered for sale inherently possessed each of the claim limitations, then the process was on sale, whether or not the seller recognized that his process possessed the claimed characteristics...
> [W]e vacate the district court's holding and remand for a determination as to whether the process on sale inherently satisfies each claim limitation.

In the instant application, inherency is established by Applicant's own disclosure. According to Applicant's teachings, beneficial effects on IgE-mediated allergy result from the administration of interferon tau. The Examiner does not question these results. However, there is nothing in Applicant's methods that differentiates the population from what is taught by the prior art, and the patient populations of the prior art would include sufferers from IgE-mediated allergy. This is because sufferers from autoimmune disease and sufferers from immune system disorders, including allergy, would include a population suffering from IgE-related allergy and such allergies would inherently have been treated by the Mujtaba et al., regardless of whether the effect was recognized at the time. Thus they would have inherently been treated for this condition regardless of whether that fact was recognized at the time. Contrary to Applicants assertions, the

Mujtaba et al. disclose that the administration of MBP induces the B cells proliferation/induction. IgE production is an inherent function of B cells. Therefore inhibition of B cells responses by interferon tau, which is disclosed by Mujtaba et al. (see abstract) would suppress or inhibit allergen-specific IgE production. Contrary to Applicants assertion that there is no teaching or suggestion in the reference of administering interferon tau to suppress or inhibit proliferation of IgE producing cells, on page 97, Mujtaba et al disclose that interferon tau inhibits B cell proliferation. Regardless of whether Mujtaba et al. disclosed interferon tau to suppressing or inhibiting proliferation of IgE producing cells, suppression or inhibition would have been inherent to the administration to interferon tau. Thus meeting the limitations of claim 28. With respect to claim 35, the disclosure of interferon administration would inherently have resulted in the suppression or inhibition of allergen-specific IgE production regardless of the need for suppression. See above in paragraph 7 for further discussion on inherency. Therefore rejection of claims 20, 21, 27, 28, 34 and 35 under 35 U.S. C 102 as being anticipated by Mujtaba et al (1998) is maintained.

9. No claims are allowable.

10. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

2/06

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER